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09/807,575	04/13/2001	Arthur Lander	82351.0003	9101

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EXAMINER	
HARRIS, ALANA M	

ART UNIT	PAPER NUMBER
1643	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	09/807,575	LANDER ET AL.	
	Examiner	Art Unit	
	Alana M. Harris, Ph.D.	1643	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *18 July 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-18* is/are pending in the application.

4a) Of the above claim(s) *7-16* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-6, 17 and 18* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Response to Arguments

1. Claims 1-18 are pending.

Claims 1-6 have been amended.

Claims 7-16, drawn to non-elected inventions are withdrawn from examination.

Claims 1-6, 17 and 18 are examined on the merits to the extent the binding molecule bind to glypican-1.

Withdrawn Rejections

Claim Rejections - 35 USC § 112

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. The rejection of claims 1-6, 17 and 18 under 35 U.S.C. 112, first paragraph, set forth on page 3 of the Action mailed April 18, 2007 as failing to comply with the written description requirement is withdrawn in view of the amendments submitted July 18, 2007.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. The rejection of claims 2-4 and 6 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter

which applicant regards as the invention is withdrawn in part in light of the amendments regarding instructions submitted July 18, 2007.

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. The rejection of claims 1-6 under 35 U.S.C. 102(b) as being anticipated by Karthikeyan et al. (Journal of Cell Science 107(part 11): 3213-3222, November 1994), as evidenced by Kleeff et al. (J. Clin. Invest. 102(9): 1662-1673, November 1998) is withdrawn in light of Applicants' amendments to the claims, however it may be reinstated with the deletion of the new matter.

8. The rejection of claims 1-6 under 35 U.S.C. 102(b) as being anticipated by Ivins et al. (Developmental Biology 184(2): 320-332, April 15, 1997), as evidenced by Kleeff et al. (J. Clin. Invest. 102(9): 1662-1673, November 1998) is withdrawn in light of Applicants' amendments to the claims, however it may be reinstated with the deletion of the new matter.

9. The rejection of claims 1-6 under 35 U.S.C. 102(a) as being anticipated by Litwack et al. (Developmental Dynamics 211: 72-87, January 1998), as evidenced by Kleeff et al. (J. Clin. Invest. 102(9): 1662-1673, November 1998) is is withdrawn in light of Applicants' amendments to the claims, however it may be reinstated with the deletion of the new matter.

10. The rejection of claims 1-6 under 35 U.S.C. 102(a) as being anticipated by Liu et al. (The Journal of Biological Chemistry 273(35): 22825-22832, August 28, 1998), as evidenced by Kleeff et al. (J. Clin. Invest. 102(9): 1662-1673, November 1998) is withdrawn in light of Applicants' amendments to the claims, however it may be reinstated with the deletion of the new matter.

Claim Rejections - 35 USC § 103

11. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

12. The rejection of claims 1-6, 17 and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Karthikeyan et al. (Journal of Cell Science 107: 3213-3222, November 1994), as evidenced by Kleeff et al. (J. Clin. Invest. 102(9): 1662-1673, November 1998), and in view of Birembaut et al. (Journal of Pathology 145: 283-296,

April 1985) is withdrawn in light of Applicants' amendments to the claims, however it may be reinstated with the deletion of the new matter.

13. The rejection of claims 1-6, 17 and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ivins et al. (Developmental Biology 184: 320-332, April 15, 1997), as evidenced by Kleeff et al. (J. Clin. Invest. 102(9): 1662-1673, November 1998), and in view of Birembaut et al. (Journal of Pathology 145: 283-296, April 1985) is withdrawn in light of Applicants' amendments to the claims, however it may be reinstated with the deletion of the new matter.

14. The rejection of claims 1-6, 17 and 18 under 35 U.S.C. 103(a) as being unpatentable over Litwack et al. (Developmental Dynamics 211: 72-87, January 1998), as evidenced by Kleeff et al. (J. Clin. Invest. 102(9): 1662-1673, November 1998), and in view of Birembaut et al. (Journal of Pathology 145: 283-296, April 1985) is withdrawn in light of Applicants' amendments to the claims, however it may be reinstated with the deletion of the new matter.

15. The rejection of claims 1-6, 17 and 18 under 35 U.S.C. 103(a) as being unpatentable over Liu et al. (The Journal of Biological Chemistry 273(35): 22825-22832, August 28, 1998), as evidenced by Kleeff et al. (J. Clin. Invest. 102(9): 1662-1673, November 1998), and in view of Birembaut et al. (Journal of Pathology 145: 283-

296, April 1985) is withdrawn in light of Applicants' amendments to the claims, however it may be reinstated with the deletion of the new matter.

Maintained Grounds of Rejection and New Grounds of Rejection

Claim Rejections - 35 USC § 112

16. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

17. The rejection of claims 1-6, 17 and 18 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement is maintained and made. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. **THIS IS A NEW MATTER REJECTION.**

Applicants have amended claims to include "an interpretive article associated with the binding molecule that provides information that overexpression of glypican-1 in a tissue as compared to a corresponding healthy tissue as evidenced by binding..." and a comparison, see claims 1 and 5. Applicants also continue to have claims that include the recitations, diagnostic test system and cell treatment system in claims 1, 5, 17 and 18. Applicants do not have support for the binding molecule comprised in any type kit, nor do Applicants have support for interpretive article associated with the binding molecule. Applicants' original claims read on a diagnostic agent and a

composition comprising a therapeutic agent, but these contemplations do not provide support for kits comprising said agents, an interpretive article and comparison between a tissue and corresponding healthy tissues.

Applicants state "[they agree] in some respect and [disagree] in others", see page 5 of Remarks, 1st paragraph. It is not clear from Applicants' retort what Applicants' concur with the Examiner about and what they do not. Applicants note there is ample support found in the examples and particularly the Figures, however Applicants do not particularly point out any one by example number, page number, line number or Figure number. After a cursory review of the specification the Examiner does not note where in the specification contemplation for this claim language can be found. The Examiner has reviewed the Figures, as well as the corresponding figure descriptions and does not note cell treatment systems, interpretive articles, diagnostic/therapeutic kits, nor test systems. While support does not need to be *ipsis verbis* [i.e., "in the same words"] to be sufficient, the claimed invention must be in possession of the inventor at the time of filing. Applicants' specification is remiss of support evidencing contemplation and possession of what the Examiner has cited herein and of record in Applicants' amended claims. Applicants must delete the new matter or adequately show where support is for the amended claims.

18. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

19. Claims 1-6, 17 and 18 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

a. Claims 1 and 5 recite an interpretive article associated with either a binding agent or a therapeutic agent. It is not clear what this article is. Accordingly, the metes and bounds cannot be determined.

b. Claims 1 and 5 lack antecedent bases for the recitations, "[t]he diagnostic kit" and "[t]he therapeutic kit listed in claims 17 and 18, respectively.

Claim Rejections - 35 USC § 102

20. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

21. The rejection of claims 1-6, 17 and 18 under 35 U.S.C. 102(b) as being anticipated by Birembaut et al. (Journal of Pathology 145: 283-296, April 1985) is maintained.

Applicants aver they disagree with the instant rejection "especially in view of the amendments herein.", see page 6 of the Remarks. Applicants conclude arguments

asserting "...not all of the elements are present in the reference.". These points of view and arguments have been carefully considered, but found unpersuasive.

Applicants' amendment including an interpretative article associated with the binding molecule or therapeutic agent is regarded as an instruction of some type by the Examiner, especially in light of its lack of definition. Applicants' inclusion of a nucleic acid capable of hybridizing with the mRNA encoding glypican-1 in the claims does not impart Birembaut teaching away from disclosing antibodies detecting glypican-1 in breast cancer samples. Birembaut also presents comparison between tissues. Hence, the rejection is maintained.

Moreover, as noted previously Applicants' attention is directed to MPEP 2106.01 and 2112.01, wherein it is noted "the USPTO personnel need not give patentable weight to printed matter absent a new and unobvious functional relationship between the printed matter and the substrate" and "[w]here the only difference between a prior art product and a claimed product is printed matter that is not functionally related to the product, the content of the printed matter will not distinguish the claimed product from the prior art", respectively, see *In re Ngai*, **>367 F.3d 1336, 1339, 70 USPQ2d 1862, 1864 (Fed. Cir. 2004). Consequently, the instant rejection is still of merit and the rejection is maintained for the reasons of record.

22. The rejection of claims 1-6 under 35 U.S.C. 102(a) as being anticipated by Liang et al. (The Journal of Cell Biology 139(4): 851-864, November 17, 1997), as evidenced by Kleeff et al. (J. Clin. Invest. 102(9): 1662-1673, November 1998) is maintained.

Applicants' arguments are essentially the same as those provided against the Karthikeyan reference. These points of view have been carefully considered, but found unpersuasive.

The Examiner's response to the instant rejection is essentially the same as that stated in response to the Karthikeyan reference and the rejection is maintained for the reasons of record.

Claim Rejections - 35 USC § 103

23. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

24. The rejection of claims 1-6, 17 and 18 under 35 U.S.C. 103(a) as being unpatentable over Liang et al. (The Journal of Cell Biology 139(4): 851-864, November 17, 1997), as evidenced by Kleeff et al. (J. Clin. Invest. 102(9): 1662-1673, November 1998), and in view of Birembaut et al. (Journal of Pathology 145: 283-296, April 1985) is maintained.

Applicants' arguments for the instant rejection are the same as those stated in response to the 102 rejections. Furthermore, Applicants aver Birembaut teach HSP in healthy cells, which is counter to the claimed subject matter and Birembaut in

combination with Liang do not render the claims obvious. These arguments and points of view have been carefully considered, but found unpersuasive.

The Examiner's response to the instant rejection is essentially the same as that stated in the Action mailed April 18, 2007, page 9 and the rejection is maintained for the reasons of record.

The instant rejection is maintained because the primary reference is still of consequence, as well as the secondary reference, Birembaut. Birembaut notes the loss of a regular pericellular arrangement of HSP corresponds to anaplasia and always related to malignancy, see page 294, column 2, last two paragraphs. Moreover, it would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to make a kit containing the glypican-1 binding molecules, as well as corresponding components. One of ordinary skill in the art would have been motivated to make a kit because test kits including compounds are packaged for the advantages of convenience and economy for the ordinarily skilled artisan or the practitioner. Kits are conveniently made to reproducibly obtain results under test conditions and it is conventional to assemble necessary reagents including compounds, such as nucleic acid and antibody binding molecules for the effective diagnosis and assessment of cancer for the convenience of the practitioner and commercial expediency.

The combination of the cited references renders the claims *prima facie* obvious as noted in the rejection presented in the FAOM, see page 11, section 16.

25. Claims 1-6, 17 and 18 under 35 U.S.C. 103(a) are rejected as being unpatentable over Liang et al. (The Journal of Cell Biology 139(4): 851-864, November 17, 1997), as evidenced by Kleeff et al. (J. Clin. Invest. 102(9): 1662-1673, November 1998), and in view of Litwack et al. (Developmental Dynamics 211: 72-87, January 1998) and Birembaut et al. (Journal of Pathology 145: 283-296, April 1985). Liang does not teach a diagnostic kit, diagnostic test system or cell treatment system comprising glypican-1 detection with a nucleic acid, wherein the human cancer cell is a breast cancer cell.

However, Birembaut teaches the detection of heparin sulphate proteoglycan also art known as glypican-1 in intraductal and intralobular carcinomas of the mammary gland with antibodies, see abstract; page 284, column 1, Material section, 2nd paragraph; page 284, column 2, Antisera section; and page 285, Mammary gland section. Litwack teaches anti-sense glypican-1 RNA probes, as well as a sense glypican-1 RNA probe, which is capable of hybriding with the mRNA encoding glypican-1, see page 79, Expression...section; and page 81, Figure 7 caption. It would have been *prima facie* obvious to one of ordinary skill in the art at the time of the claimed invention was made to assay breast cancer cells for glypican-1 as taught by Birembaut, as well as implement a nucleic acid probe. Birembaut notes the loss of a regular pericellular arrangement of HSP corresponds to anaplasia and always related to malignancy, see page 294, column 2, last two paragraphs. One of ordinary skill in the art would have been motivated to combine the teachings of all of the references with a reasonable expectation of success by teachings in the Birembaut reference because

several organ types with benign and malignant cancer, including breast cancer cells were evaluated for glypican-1 with a glypican-1 antibody and Litwack because a glypican-1 nucleic acid probe for glypican-1 detection.

Moreover, it would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to make a kit containing the glypican-1 binding molecules, as well as corresponding components. One of ordinary skill in the art would have been motivated to make a kit because test kits including compounds are packaged for the advantages of convenience and economy for the ordinarily skilled artisan or the practitioner. Kits are conveniently made to reproducibly obtain results under test conditions and it is conventional to assemble necessary reagents including compounds, such as nucleic acid and antibody binding molecules for the effective diagnosis and assessment of cancer for the convenience of the practitioner and commercial expediency.

26. Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Alana M. Harris, Ph.D. whose telephone number is (571)272-0831. The Examiner works a flexible schedule, however she can normally be reached between the hours of 7:30 am to 6:30 pm, with alternate Fridays off.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Larry R. Helms, Ph.D. can be reached on (571) 272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

ALANA M. HARRIS, PH.D.
PRIMARY EXAMINER

Alana M. Harris, Ph.D.
30 September 2007